

PATENT
USSN 10/054,611
Docket 002970US; 018/182c

REMARKS

This paper is responsive to the Office Action dated December 8, 2004, which is the third non-final action on the merits of the application.

Claims 1-19, 21, and 35-46 were pending and under examination; claims 23-26 were withdrawn from examination. Upon entry of this Amendment, certain claims are cancelled or amended, and claims 47-66 are added. As a result, claims 1-9, 13-16, 23, 35, 37, 39-41, 43, and 45-66 are now pending. All but claims 23 and 65 fall within the group under examination, for which rejoinder is requested, as explained below.

Applicants acknowledge with gratitude withdrawal of the objections to the specification and the drawings.

Reconsideration and allowance of the application is respectfully requested.

Interview Summary:

The undersigned wishes to express his gratitude to Examiner Malgorzata Walicka and Examiner Rebecca Prouty for the helpful and constructive interviews held at the Patent Office on March 3, 2005, and by telephone on May 26, 2005. Amendments and remarks discussed at the interview are reproduced in this paper, and are believed to place this application in condition for allowance.

Amendments:

The amendments to the claims are supported by the claims as previously presented and throughout the specification, and do not introduce new matter into the disclosure. Specifically, claims to methods for detecting or identifying a hTERT encoding nucleic acid in a sample by hybridization or amplification assay are now split into claims where at least one of the reagents contain sequences related to SEQ. ID NO:62 (claims 47-66), or sequences related to a portion of SEQ. ID NO:224 not found in SEQ. ID NO:62 (claims 1-9, 13-16, 23, 35, 37, 39-41, 43, and 45-46). Amongst all the claims, coverage is retained for the entirety of SEQ. ID NO:224. Accordingly, the claims include coverage for all equivalents for which applicants were previously entitled.

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Rejections under 35 USC § 112 ¶ 2:

Applicants acknowledge with gratitude withdrawal of the rejection of claim 1.

Claims 2-12 and 40 stand rejected on the basis that the claims do not recite the hybridization conditions.

It is respectfully submitted that these claims do not need to indicate the reaction conditions of the hybridization step, because the hybridization referred to is not used to define what nucleic acid sequences are included in the claim. Instead, the nucleotides are defined explicitly in the last part of the claim, where it is stated that they have sequences that are identical or complementary to 25 or more consecutive nucleotides from the hTRT encoding region of SEQ. ID NO:224. This is different from claims 1, 13, 47, and 57, where the nucleotides are defined according to their hybridization properties, and the hybridization conditions are given.

Since claims 2-12 and 40 particularly point out and distinctly claim the nucleic acid sequences present in the probes and primers used in the claimed methods, they comply with the requirements of § 112 ¶ 2. The user may readily determine what hybridization conditions should be used for a particular probe or primer to provide a specific test, using standard textbooks for nucleic acid manipulation and testing, including but not limited to conditions exemplified in the application.

Claims 2-12, 14-19, 21, and 40 stand rejected under § 112 ¶ 2 as being indefinite. Specifically, the Office Action indicates that the meaning of the phrase "consisting essentially of" is unclear in view of the explanation given previously.

In response, applicants submit the following clarification. A nucleic acid "consisting essentially of" a particular sequence means that the nucleic acid may contain additional nucleotides or other elements, so long as the additional features do not prevent the nucleic acid from exercising the function indicated in the claims. In particular:

- Claims 2, 52, and their dependents cover the use of the nucleic acid as a probe. Any additional features of the nucleic acid (if present) do not prevent the probe from hybridizing specifically with SEQ. ID NO:224 or its complement.
- Claims 14, 62, and their dependents cover the use of the nucleic acid as an amplification primer. Any additional features of the nucleic acid (if present) do not prevent the primer from specifically amplifying the corresponding portion of SEQ. ID NO:224.

Withdrawal of these rejections is respectfully requested.

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Rejections under 35 USC § 103

The claims as previously presented stand rejected under § 103(a) as being unpatentable over the sequence tag designated AA281296, in view of the paper by Lingner et al., Science 276:561-567, 1997. Specifically, the Office Action indicates that both references are prior publications (supposing the application is only entitled to a May 6, 1997 filing date), and asserts that the Lingner reference motivates the reader to find AA281296 using the *E. aediculatus* telomerase sequence.

Applicants disagree that the Lingner article constitutes prior art "by another", that there is motivation to combine the references in the manner indicated, or that the combined references place the invention claimed here in the hands of the public. It is unnecessary to elaborate, because the claims have now been amended to remove the combination of references from consideration altogether.

Claims 1-9, 13-16, 23, 35, 37, 39-41, 43, and 45-46 now require that the reagent(s) used to conduct the assay method contain sequences related to a portion of SEQ. ID NO:224 not found in SEQ. ID NO:62. (AA281296 corresponds to SEQ. ID NO:62.) Accordingly, these claims are patentable over the cited references *inter alia* because the references do not teach or suggest alone or in combination any of SEQ. ID NO:224 not found in SEQ. ID NO:62.

New claims 47-66 require that the reagent(s) used to conduct the assay method contain sequences related to SEQ. ID NO:62. These claims enjoy the priority benefit of USSN 08/844,419, filed April 18, 1997; and USSN 08/846,017, filed April 25, 1997. These applications disclose SEQ. ID NO:62, and teach the use of SEQ. ID NO:62 in assays for detecting hTERT nucleic acids (see U.S. Patent No. 6,808,880, which is a continuation of USSN 08/846,017). Since these claims are entitled to an April priority date, the Lingner article cannot be a prior art reference.

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Related applications:

Under 37 CFR § 1.56, applicants wish to remind the attention of the Examiner the other issued and pending applications in this series relating to sequences for telomerase reverse transcriptase.

- Issued patents for hTRT include U.S. 6,475,789; U.S. 6,261,836; U.S. 6,617,110; and U.S. 6,808,880.
- Allowed applications for hTRT include USSN 09/438,486; 09/843,676; and 10/054,295.
- The other pending applications for hTRT include USSN 08/974,584; 09/432,503; 09/721,477; 09/721,506; 10/053,758; 10/054,611; 10/044,692; 10/877,022; 10/877,124; 10/044,539, and 10/877,146.
- Patents claiming TRT from single cell ciliates include U.S. 6,093,809; U.S. 6,166,178; and U.S. 6,309,867.
- Patents and patent applications for mouse TRT include U.S. 6,767,719 and USSN 10/862,698.
- Patents and applications for the hTRT promoter include U.S. 6,610,839; U.S. 6,777,203; USSN 10/325,810; and USSN 10/674,836.
- Patents and applications for hTRT variants include U.S. 6,337,200 and USSN 09/990,080.
- Patents and applications for hTRT antisense oligonucleotides include U.S. 6,444,650; U.S. 6,627,619; and USSN 10/637,443.

The undersigned is not aware of any double patenting issue or prosecution issue that should affect the patentability of the claims in this application. However, the Examiner is invited to do her own assessment.

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Request for Rejoinder:

Applicants hereby renew their request to rejoin claims 23 and 65 back into the group under examination. Other claims withdrawn from examination have been cancelled.

Even though the claims are not rejoinable as a matter of right, applicants submit that these claims can be examined together with the elected group without raising substantive new issues under 35 USC §§ 101, 102, 103, or 112.

These claims depend from and incorporate limitations of claims in the elected group. Specifically, the oligonucleotide primers of claim 23 have the following features:

- they consist essentially of 15 or more consecutive nucleotides of SEQ. ID NO:224 not contained in SEQ. ID NO:62
- they are suitable for use in the amplification detection method of claim 14.

In determining the patentability of claim 14, the Examiner has already determined that oligonucleotides found in SEQ. ID NO:224 but not SEQ. ID NO:62 were not previously known. On this basis, the product of claim 62 is also free of the prior art. Since the probes of claim 23 can be made and used in the method of claim 14, it follows that they are described and enabled by the application to the extent required by 35 USC § 112.

By the same reasoning, the product of claim 62 has the features of the probes used in claim 47, and must satisfy all the requirements of patentability.

Since there are no substantial new issues of patentability, there would be no burden on the Office in rejoining the withdrawn claims. Accordingly, applicants respectfully request that claims 23 and 65 be rejoined, in order to save applicants the financial burden and delay of having to file a divisional application to protect this important embodiment of the invention.

Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event the Examiner determines that there are other matters to be addressed, applicants hereby request an interview by telephone.

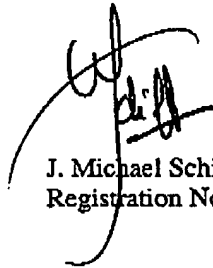
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Fees Due

Enclosed with this Amendment is authorization to charge the Deposit Account for the extension of time and the new claims.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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